EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

INDIVIOR INC. *f/k/a* RECKITT BENCKISER PHARMACEUTICALS INC., and AQUESTIVE THERAPEUTICS, INC. *f/k/a* MONOSOL RX, LLC, Plaintiffs, v. BIODELIVERY SCIENCES INTERNATIONAL, INC. Defendant.	Civil Action No.: 5:15-cv-00350-D

PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION
PURSUANT TO RULE 34 (NOS 1-12)

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and all applicable Local Civil Rules of the United States Court for the Eastern District of North Carolina, Plaintiffs Aquestive Therapeutics, Inc. ("Aquestive") and Indivior Inc. ("Indivior"), (collectively, "Plaintiffs"), request that Defendant BioDelivery Sciences International, Inc. ("Defendant" or "BDSI") answer separately and completely in writing within thirty (30) days of service hereof each of the requests set forth below and produce documents, at the offices of Steptoe and Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036. The following Requests are governed by the Definitions and Instructions set forth herein.

DEFINITIONS

The following Definitions apply throughout these Requests, regardless of whether upper- or lower-case letters are used:

1. The term "Aquestive" means Plaintiff Aquestive Therapeutics, Inc., and includes,

without limitation, all parents, subsidiaries, affiliates, divisions, officers, directors, employees, partners, agents, attorneys, and representatives of Aquestive, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of Aquestive.

2. The term "Indivior" means Plaintiff Indivior, Inc., and includes, without limitation, all parents, subsidiaries, affiliates, divisions, officers, directors, employees, partners, agents, attorneys, and representatives of Indivior, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of Indivior.

3. The term "Plaintiffs" means Plaintiff Aquestive and/or Plaintiff Indivior, individually or collectively, and includes, without limitation, all parents, subsidiaries, affiliates, divisions, officers, directors, employees, partners, agents, attorneys, and representatives of either Aquestive or Indivior, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of either Aquestive or Indivior.

4. The terms "Defendant," "BDSI," "You" and "Your" mean Defendant BioDelivery Sciences International, Inc., and includes, without limitation, all parents, subsidiaries, affiliates, divisions and other entities owned or controlled by Defendant, if any; all officers, directors, employees, partners, agents, attorneys, representatives and owners (whether direct or indirect and legal, beneficial or otherwise) of entities owned or controlled by Defendant, if any, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of Defendant or of any subsidiary, affiliate, division or entity owned or controlled by Defendant

5. The terms "'167 patent" and "patent-in-suit" mean U.S. Pat. No. 8,765,167.

6. The term "Asserted Claims" means claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100, 103, 105, 107, 108, 117 and 118 of the '167 patent, and any other claim of the '167 patent identified by Plaintiffs in a disclosure pursuant to E.D.N.C. Local Patent Rule 303.1(a).

7. The terms "this litigation" and "this matter" mean Plaintiffs' infringement suit against

BDSI, Civil Action No. 5:15-cv-00350-D.

8. The term "Defendant's NDA" means BDSI's New Drug Application ("NDA") No. 205637, submitted under 21 U.S.C. § 505(b)(2), seeking approval to manufacture, market and sell BUNAVAIL throughout the United States, which was approved by the FDA on June 6, 2014, including any amendments and communications to or from the FDA relating to the NDA.

9. The terms "BUNAVAIL" and "Accused Product" means Defendant's BUNAVAIL® (buprenorphine and naloxone) buccal film products that are the subject of Defendant's NDA in the following doses: 2.1 mg buprenorphine/0.3 mg naloxone; 4.2 mg buprenorphine/0.7 mg naloxone; and 6.3 mg buprenorphine/1.0 mg naloxone.

10. The term "FDA" means the United States Food and Drug Administration.

11. The terms "Person" and "Persons" means any individual or entity, including, without limitation, a corporation, municipal corporation, partnership, joint venture, firm, trust, group association, governmental agency, commission, bureau or department and any division, department or other unit thereof.

12. The term "Entity" means any entity, including, without limitation, a corporation, municipal corporation, partnership, joint venture, firm, trust, group association, governmental agency, commission, bureau or department and any division, department or other unit thereof.

13. The term "Third Party" means and includes any Person or Entity other than Defendant and Plaintiffs.

14. The term "communication" means the transmission of information (in the form of facts, ideas, inquiries or otherwise), whether orally or in writing (e.g., by fax, email, or any other means or medium), and includes without limitation all documents reflecting or concerning such communications.

15. The terms "thing" or "things" shall be defined as synonymous in meaning and equal

in scope to the use of that term in Fed. R. Civ. P. 34(a) and includes any tangible object other than a document.

16. The term "document" is used in the broadest sense contemplated by Federal Rule of Civil Procedure 34 and includes the terms "writings and recordings," "photographs," "originals," and "duplicate" as defined in Federal Rule of Evidence 1001 and includes, without limitation, any and all tangible documents and things responsive to the document request as well as any other information regardless of the form in which the information has been stored, including electronically stored information within Your possession, custody, or control.

17. The term "communication" means the transmittal of information in the form of facts, ideas, inquiries or otherwise, orally, in writing, or in any other form including, but not limited to, documents, conversations, correspondence, telephone calls, e-mails, facsimiles, and text messages, whether sent or received via internet, cellular data, or text/short message service.

18. The terms "electronically stored information" or "ESI" mean any document, communication, code, architecture, internal software comments, or any other data or information present or stored on any computer, internal or external hard drive, jump drive, diskette, compact disc, database, server, or any other device or system capable of storing electronic files or information.

19. The terms "reflecting," "concerning," "regarding," "relating to," or "referring to" mean all documents or information that comprises, evidences, constitutes, describes, explicitly or implicitly refers to, was reviewed in conjunction with, or was generated as a result of the subject matter of the request, including but not limited to all documents that reflect, record, memorialize, discuss, evaluate, consider, review, report, or relate to the subject matter of the request.

20. The terms "infringe" and "infringement" mean and refer to any and all types of infringement set forth in 35 U.S.C. § 271, including direct infringement, contributory infringement, inducement of infringement, literal infringement, and/or infringement under the doctrine of

equivalents.

21. The term "employee" means any person currently or formerly serving, acting, or existing as an employee or agent, including employees, agents, attorneys, partners, associates, financial advisors, consultants, investigators, and any other person acting on behalf of the person referred to, pursuant to the authority of the person referred to, or subject to the control of the person referred to.

22. The term "identify" when used with respect to an activity, an occasion or a transaction means and refers to providing: the date of the act; the identity of the persons who participated in the act; the identity of each person who witnessed such act; and a general description of the act.

23. The term "identify" when used with respect to persons means to state the person's name, title (or job description), present or last known employer or business association, and present or last known address.

24. The term "identify" when used with respect to documents means to provide the following information irrespective of whether the document is deemed privileged or subject to any claim of privilege:

a) the title or other means of identification of the document;

b) the date of the document;

c) the author of the document;

d) the recipient or recipients of the document;

e) the subject matter of the document;

f) the present location of any and all copies of the document in the possession, custody or control of Defendants; and

g) the names and current addresses of any and all persons who have possession, custody, or control of the document or copies thereof.

25. “And” and “or” shall be construed conjunctively and disjunctively so as to acquire the broadest possible meaning.

26. The terms “any,” “all,” or “each” shall be construed as “any, all and each.”

27. The singular and masculine form of a noun or pronoun shall embrace, and shall be read and applied as, the plural or the feminine or neuter, as the particular context makes appropriate or permits to obtain the broadest possible meaning.

28. The use of the singular form of any word shall include the plural and vice versa.

INSTRUCTIONS

1. These discovery requests extend to all documents in the possession, custody, or control of Defendant, and/or in the possession, custody, or control of any and all of Defendant’s Entities and Affiliates, and/or in the possession, custody, or control of any and all other Entities whom Defendant and/or its Entities or Affiliates direct or control, or otherwise available to Defendant.

2. In the event more than one copy of a document exists, Defendant shall produce the original and each non-identical copy of each document or other tangible thing requested herein.

3. Each discovery request shall be fully responded to unless it is in good faith objected to, in which event the reasons for your objection shall be stated in detail. If an objection pertains only to a portion of a discovery request, or a word phrase, or clause contained within it, you are required to state your objection to that portion only and to respond to the remainder of the discovery request, using your best efforts to do so.

4. To the extent Defendant alleges that the meaning of any term in these discovery requests is unclear, Defendant is to assume a reasonable meaning, state that assumed reasonable meaning and respond to the request on the basis of that assumed meaning.

5. All requested documents produced by Defendant shall be organized either to

correspond to the categories in these discovery requests, or as they are kept in the ordinary course of business. In either case, all documents produced shall:

(a) be produced with all associated file labels, file headings, and file folders together with the responsive documents from each file, and each file shall be identified as to its owner or custodian; for any document originally stored in electronic media, the file name, path, and directory information for each such documents shall also be provided;

(b) if produced in hard copy, all pages now stapled or fastened together shall be produced stapled or fastened together, and shall include all attachments currently or previously appended to each document, regardless of whether such attachments themselves are responsive to these requests;

(c) if produced electronically, all attachments currently or previously appended to the electronic file shall be produced, regardless of whether such attachments themselves are responsive to these requests;

(d) all documents that cannot be legibly copied shall be produced in original form.

6. If any document identified in response to any of these discovery requests was, but is no longer in the possession, custody, or subject to the control of Defendant, or is no longer in existence, state whether it:

(e) is missing or lost;

(f) has been destroyed;

(g) has been transferred, voluntarily or involuntarily, to others and state the identity of those persons to whom it has been transferred;

(h) has been otherwise disposed of, and in each instance, explain the circumstances surrounding such disposition, state the date or approximate date thereof, and the identity of the persons with knowledge of such circumstances; or

(i) identify the writings that are missing, lost, destroyed, transferred, or otherwise disposed of, by author, date, subject matter, addressee, and the number of pages.

7. With respect to any claim of a privilege by Defendant regarding any information, document, or communication sought by any of Plaintiffs' discovery requests, and consistent with Federal Rules of Civil Procedure 26(b)(5), Defendant is requested to individually identify each such communication, information, or document withheld on grounds of an alleged privilege, and specifically set forth:

(a) the nature of the privilege claimed, as well as the grounds for withholding the communication, document, or information, including the specific facts upon which you rely upon to establish the privilege;

(b) the nature of the communication, document, or information, whether written, oral or both;

(c) the author(s) or speaker(s), as well as their titles and positions;

(d) all addressee(s), as well as their titles and positions;

(e) all persons who received copies, as well as their titles and positions;

(f) the date of the communication, document, or information;

(g) the subject matter of the communication, document, or information; and

(h) the specific document requests to which the communication, document, or information is responsive.

8. Each discovery request shall be construed independently and not with reference to any other discovery request for the purpose of limitation.

9. None of the discovery requests shall be construed as an admission relating to the existence of any evidence, to the relevance or admissibility of any evidence, or to the truth or accuracy of any statement or characterization in the discovery request.

10. Pursuant to Rule 26(e) of the Federal Rules of Civil Procedure, these requests are deemed to be continuing in nature to the full extent required by the Federal Rules of Civil Procedure. If further

responsive documents come into the possession or to the attention of Defendant or its attorneys at any time during the course of this litigation, such documents must be produced as required by the Federal Rules of Civil Procedure.:

REQUESTS FOR PRODUCTION OF DOCUMENTS

REQUEST FOR PRODUCTION NO. 1:

All documents and things concerning Defendant's NDA, including the full and complete NDA, all documents and things submitted to the FDA in connection with Defendant's NDA, any supplements or amendments to Defendant's NDA, and all drafts of any of the above.

REQUEST FOR PRODUCTION NO. 2:

All documents and things considered or relied upon by Defendant in preparation of Defendant's NDA and any amendments or supplements thereof.

REQUEST FOR PRODUCTION NO. 3:

All documents and things concerning any correspondence or communication relating to Defendant's NDA and/or BUNAVAIL, including any and all correspondence or communications to or from the FDA concerning Defendant's NDA, including any and all NDA amendments and supplements.

REQUEST FOR PRODUCTION NO. 4:

All documents and things reflecting all components of BUNAVAIL, including all active ingredients and inactive ingredients or excipients, and including an identification of the purpose of each component and the amount of each component contained in BUNAVAIL.

REQUEST FOR PRODUCTION NO. 5:

All documents and things concerning the manufacture or testing of BUNAVAIL without regard to whether such testing was reported to the FDA.

REQUEST FOR PRODUCTION NO. 6:

All documents and things reflecting the procedures and processes used to manufacture Defendant's BUNAVAIL products, including, but not limited to, a description of all mixing, casting, drying, and coating steps, and a description of any changes to those manufacturing procedures and processes starting from the date the FDA approved BDSI's NDA (i.e., June 6, 2014) through and including the present.

REQUEST FOR PRODUCTION NO. 7:

All documents and things concerning the formulation and manufacture of Defendant's BUNAVAIL products, including any and all work done by Defendant or done at the Defendant's instruction or for a Defendant's benefit by others, to develop the formulation, the amounts and proportions of all ingredients and materials used in the formulation, and all associated processing methods and manufacturing steps.

REQUEST FOR PRODUCTION NO. 8:

All documents and things concerning the drying process for Defendant's BUNAVAIL products that Defendant considered, tested, evaluated, or proposed for submission to the FDA, or submitted to the FDA.

REQUEST FOR PRODUCTION NO. 9:

All documents and things concerning testing, evaluation, or measurements conducted by or on behalf of BDSI related to the amount and distribution of active ingredients in Defendant's BUNAVAIL products, including, but not limited to testing, evaluations, or measurements of the amount and distribution of active ingredients in an individual dosage unit and/or the variation of the amount and distribution of active ingredients between individual dosage units.

REQUEST FOR PRODUCTION NO. 10:

All documents and things concerning methods, calculations, and analyses related to

determining the amount and distribution of active ingredients, in any pharmaceutical film product created during the development of, or tested for the purpose of developing, Defendant's BUNAVAIL products.

REQUEST FOR PRODUCTION NO. 11:

All documents and things related to or referring to process flow specifications performed or investigated during production or development of Defendant's BUNAVAIL products, including ingredients, amounts, mixing, casting, drying steps and detailed diagrams and/or photographs of the apparatuses used in each step.

REQUEST FOR PRODUCTION NO. 12:

All documents and things relating to Defendant's assertions that Defendant's BUNAVAIL products do not infringe and will not infringe the patents-in-suit, including all such information that Defendant contend support those positions or which tends to undermine or contradict such contentions.

Date: June 1, 2021.

Respectfully submitted,

/s/ E. Bradley Evans

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CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2021, I have served the foregoing documents on all counsel of record.

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